

REMARKS

Status of the Claims

Claims 1, 3-8 and 21-30 are currently pending. Claims 22-30 have been withdrawn as being drawn to non-elected inventions. Claims 1, 3-8 and 21 were examined. Claims 1, 3-8 and 21 presently stand rejected.

Claim 1 is amended and claim 21 is canceled, the subject matter of which is not disclaimed. Applicants reserve the right to pursue the removed subject matter in another application for patent.

Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1, 3-8 and 21 stand rejected as allegedly failing to comply with the written description requirement of 35 U.S.C. § 112. The Office contends “the instant application does not specifically disclose which individual genes or combination thereof would provide gene expression profiles that can be used to diagnose RCC specifically,” (Office action, p. 7, last paragraph breaking over to the top of p. 8). The Office further contends that the “specification does not provide combinations of genes that can be used to differentiate RCC from other tumor diseases,” (Office action, p. 10, lines 12-14.)

Claim 1 is amended to be drawn to a method of “confirming a diagnosis of RCC” in a human who has been previously diagnosed with RCC by generating an expression profile comprising two markers, TLR2 and EEF1A2. Claim 21 is canceled, since its subject matter has been imported into claim 1.

Claim 1 as amended has written description support at, e.g., paragraph 26 of the published specification and in Example 6, which describes the accuracy of predicting whether a sample is RCC or RCC-free based on a two (2) gene class predictor. In that example, TLR2 and EEF1A2 were used as co-markers to predict whether the human from which the PBMCs were obtained was previously diagnosed with RCC. According to Table 8 of the instant specification, the combination of TLR2 and EEF1A2 had a prediction accuracy of 100% for the test set of PBMCs, which means that the PBMC test confirms the prior diagnosis of RCC with 100% accuracy. Thus, claim 1 as amended was actually reduced to practice and therefore has full written description support.

In view of the amendment to claim 1, from which all remaining pending claims depend, Applicants submit that the claims comply with the written description requirement. Applicants

request that the Office withdraw its rejection of the claims under 35 U.S.C. § 112, first paragraph, written description.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 3-8 and 21 stand rejected for allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112. The Office asserts that “although the instant specification teaches examples of comparing expression profiles [of] RCC samples [to] disease-free samples, the instant specification does not provide all possible combination of genes or individual genes that can be used to differentiate RCC from other tumor diseases,” (Office action, p. 15, lines 9-13).

As described above, Applicants amend claim 1 to be directed to confirming a diagnosis of RCC in a patient with a prior diagnosis of RCC, using a combination of two markers, TLR2 and EEF1A2. As such, claim 1 and its dependent claims are fully enabled, as they are supported by, e.g., Example 6. Therefore, Applicants request that the Office withdraw its rejection of the claims under the enablement requirement of 35 U.S.C. § 112, first paragraph.

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CONCLUSION

In view of the foregoing amendment and discussion, applicants submit that the present application is in condition for allowance. Reconsideration and allowance are respectfully requested.

If a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at (973) 660-6613.

Respectfully submitted,

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